

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

June 11, 2015

Tunothy C. Dolo

MEMORANDUM:

SUBJECT: Review of MRID 49496601 "Release Properties and Data Program Review AGS-20",

HeiQ Study Number HQE-A-011.

PC Code: 072599	DP Barcode: 424419
Decision No.: 498070	Registration No.: 85249-1
Petition No.: NA	Regulatory Action: Conditional Registration Follow-up
Risk Assess Type: NA	Case No.: NA
TXR No.: NA	CAS No.: NA
MRID No.: 49496601	40 CFR: NA

FROM:

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THRU:

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TO:

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This submission is a review of studies that have been submitted by HeiQ to address the Tier I release studies that were required for the conditional registration of AGS-20. The Tier I release studies included a non-guideline textiles leaching study, a non-guideline dissolution kinetics study and series 830.6313 stability to normal and elevated temperatures and metals/metal ions study. These studies have either been waived or reviewed. In addition, the information in this submission does not change the data requirements that are listed in the EPA Memorandum "Updated Data Requirements for the conditional registration of HeiQ AGS-20" of December 11, 2014.

Studies Included in the HeiQ Release Properties and Data Program Review

Series 830.6313 stability to normal and elevated temperatures and metals/metal ions study

The series 830.6313 stability study was required to assess the exposures to workers handling AGS-20 powder. This study is no longer needed because AGS-20 is now packaged in water soluble packaging which greatly reduces the potential for exposure.

Non-guideline textiles leaching study

This study was submitted as MRID 49141001 and an expanded version of this study, that included four additional silver treated fabrics, was published in the open literature (Mitrano et al, 2014). EPA reviewed the submitted study in D414798 (US EPA, 2015). While this review focused primarily on the submitted study, the open literature version of the study was also consulted.

Non-guideline dissolution kinetics study

This study was submitted as MRID 49203401 and a corrected version was submitted as 49327301. EPA reviewed the study in D415003 (US EPA, 2014). This review included the correction.

Conclusion

EPA has either waived or previously reviewed the studies included in the HeiQ Release Properties and Data Program Review. The information in the HeiQ review does not change the data requirements that are listed in the EPA Memorandum "Updated Data Requirements for the conditional registration of HeiQ AGS-20" of December 11, 2014.

References:

Mitrano et al, 2015. Presence of Nanoparticles in Wash Water from Conventional Silver and Nano-silver Textiles, Mitrano, D.M., Rimmele, E., Wichser, A., Ermi, R., Height, M., and Nowack, B., ACS Nano, 2014, 8(7), pp 7208-7219, June 18, 2014

US EPA, 2014. Review of "Non-Guideline Dissolution Kinetics Study" of HeiQ AGS-20, EPA Memorandum D415003, March 26, 2014.

US EPA, 2015. Review of MRID 49141001 "Release of silver from textiles", HeiQ Study Number HQE-A-005. EPA Memorandum D414798, May 21, 2015.